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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,989	09/10/2003	Jan Bastiaan Bouwstra	BOUWSTRA-3	6068
545	7590	11/24/2004	EXAMINER	
ANTHONY H. HANDAL KIRKPATRICK & LOCKHART, LLP 599 LEXINGTON AVENUE 31ST FLOOR NEW YORK, NY 10022-6030			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 11/24/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/658,989	Applicant(s) BOUWSTRA ET AL.	
	Examiner Anand U Desai, Ph.D.	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on September 7, 2004. New claims 16-30 have been added. Claims 1-30 are currently pending and are under examination.

Withdrawal of Rejections

2. The rejection of claim 2 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out the monomer molecular weight is withdrawn.
3. The rejection of claims 1-4, 6, 9-12, and 14 under 35 U.S.C. § 102(b) as being anticipated by HAEMACCEL package insert is withdrawn.
4. The rejection of claims 1-4, 6, 9-12, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Ecanow et al. U.S. Patent 4,539,204 in view of HAEMACCEL package insert is withdrawn.

Maintenance of Objections and Rejections

Specification

5. The disclosure is objected to because of the following informalities:

There are multiple instances through out the specification where the words, "amino acid" are missing a space between them, for example on page 8, lines 16, 21, and page 10, line 14. The sentence on page 9, beginning on line 4, appears to be missing the word "can" after the words "..comprising gelatins..". There is a typographical error on page 10, line 5, the word "serie" appears to be intended to be "series". The abbreviation on page 10, line 10 of IEP is undefined, suggest writing it as "isoelectric point (IEP)" at the first appearance. The words, "bloodplasma" is missing a space between the two words on page 14, line 31. The words, "bloodvessels" is missing a space between the two words on page 15, lines 3, and 4. There is a

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typographical error on page 22, the “4oC” in the remarks section appears to be intended to be “4°C”. On page 23, line 10, the word red blood cell should be spelled out prior to using the abbreviation “rbc”.

Appropriate correction is required.

Claim Objections

6. Claim 3 is objected to because of the following informalities:
7. There is a typographical error. A space is missing between the number “1” and the word “wherein”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claims 3, 5, and 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
10. Claim 3 recites the limitation "the recombinant gelatin-like protein monomer" in the 1st sentence. There is insufficient antecedent basis for this limitation in the claim.
11. In claim 5, there is no particular sequence disclosed that one could determine the positively, and negatively charged amino acids. In addition, in claim 5 the word “preferably” makes the claim indefinite. Is it greater than 2 or 3?
12. In claim 7, there is no particular sequence disclosed that one could determine the location of replacement of glutamine by glutamic acid and/or replacement of asparagines by aspartic acid.

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Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

14. Claims 1-4, 6, 9-12, 14, 18, 19, 21, 24, 25, and 27 are rejected under 35 U.S.C. 102(a) as being anticipated by Chang, C. et al. (WO 01/34646 A2). Chang, C. et al. disclose a composition comprising recombinant gelatin having a molecular weight range from about 0 to 50 kDa. Chang, C. et al. disclose a plasma expander comprising recombinant gelatin, and a colloidal volume replacement material comprising recombinant gelatin. Chang, C. et al. discloses the ability to produce recombinant gelatin with desired isoelectric profile, pH, degree of hydroxylation, and amino-acid compositions (see page 7, line 36 – page 8, line 10, page 28, lines 34-36, page 35, lines 29-37, page 58, lines 5-10, and claims 3, 56, and 57, current application, claims 1-4, 6, 9-12, 14, 18, 19, 21, 24, 25, and 27).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang, C. et al. (WO 01/34646 A2) in view of Olsen et al. U.S. 6,413,742 B1. Chang, C. et al. disclose a composition comprising recombinant gelatin having a molecular weight range from about 0 to 50 kDa. Chang, C. et al. disclose a plasma expander comprising recombinant gelatin, and a colloidal volume replacement material comprising recombinant gelatin. Chang, C. et al. discloses the ability to produce recombinant gelatin with desired isoelectric profile, pH, degree of hydroxylation, and amino-acid compositions (see page 7, line 36 – page 8, line 10, page 28, lines 34-36, page 35, lines 29-37, page 58, lines 5-10, and claims 3, 56, and 57). Chang, C. et al. does not disclose the recombinant gelatin-like protein comprising SEQ ID NO: 1.

Olsen et al. discloses a method to produce recombinant human type I collagen proteins. The method can be used to make any fibrillar collagen, as well as the corresponding types of gelatin for use in medical applications (see U.S. Patent '742, column 3, lines 44-55, and column 4, lines 7-36). One would have been motivated to use the recombinant method disclosed by Olsen et al. to produce a gelatin composition that would have no risk of contaminants such as bovine spongiform encephalopathy (BSE), or Creutzfeldt-Jakob disease.

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Therefore, it would have been obvious to a person having ordinary skill in the art to use the method of Olsen et al. to produce a recombinant gelatin protein with the desired isoelectric profile, and amino acid composition as disclosed in Chang, C. et al. to produce a composition suitable as a substitute for plasma substitute, comprising a modified collagen polypeptide (current application, claims 1-30).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 19, 2004



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER